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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,548	02/05/2002	David W. LaFleur	PZ024P1C1	3544
22195	7590	02/09/2004	EXAMINER	
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

10/062,548

## Applicant(s)

LAFLEUR ET AL.

## Examiner

Young J. Kim

## Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17, 19, 20, 30-35, 41-45 and 51-71 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-35, 41-45 and 51-63 is/are allowed.
- 6) ☒ Claim(s) 64-66 is/are rejected.
- 7) ☒ Claim(s) 20 and 67-71 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action responds the Amendment received on November 6, 2003.

#### *Election/Restrictions*

Preliminarily, Examiner of record affirms the typographical error introduced in the Office Action mailed on July 28, 2003, wherein the correspondence indicated that claim 20 was withdrawn from further consideration for being drawn to non-elected invention. The typographical error resulted because claim 20 was dependent on a canceled claim 11 and Applicants have not amended the claim appropriately to establish correct dependency. As such was a typographical error, the claim is included in the instant prosecution.

Additionally, on page 7 of Applicants' response, Applicants state that rejoinder of Group II (under examination), Group IV (claim 17), and Group VI (claim 19) requested once the claims of Group II are found allowable. Applicants appear to be appealing to the precedence set in *In re Ochiai*. The Office practice with regard to the *Ochiai* is as follows:

When the examiner requires a restriction between product and process claims and where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.**

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). **Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution** either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of right to rejoinder.**

Further, note that the prohibition against double patenting rejection of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Finally, Applicants are advised that in the event of rejoinder, if the application containing the rejoined claims is not in condition for allowance, the subsequent Office Action may be made FINAL, or, if the application was already under FINAL rejection, the next Office Action may be made an advisory action.

Since the process claims of 17 and 19 have not been amended “during prosecution” to maintain dependency on the product claims nor have the claims been amended to include the limitations of the product claims, Applicants are advised that rejoinder *right has been lost*.

However, in order to facilitate compact prosecution, Applicants are advised that Group VI (claim 19) will be available for rejoinder when Applicants’ subsequent response establishes a proper dependency of the claim. Further, the patentability of the instant polypeptide has been determined with regard to its use as a diagnostic marker. Therefore, with regard to the process claim 17 of Group IV, drawn to a process of using the polypeptide to prevent, treat, or ameliorate a medical condition, the process of use claim is not “commensurate in scope with the product” resulting in new issues with regard to enablement, precluding compact prosecution, and for this reason, the rejoinder offer is *not* extended.

For the above reasons, claims 17 and 19 remain withdrawn.

This application contains claims 17 and 19 drawn to an invention nonelected with traverse in the Election received on May 9, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

The objection of claims 11 and 12 for failing to recite the elected invention (*i.e.*, SEQ ID NO: 97), made in the Office Action mailed on July 28, 2003 is withdrawn in view of the Amendment received on November 6, 2003, canceling the claims.

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***Claim Objections***

Claim 20 is objected to for depending on claims drawn to elected invention.

***Claim Rejections - 35 USC § 112***

The rejection of claims 11, 12, and 46-55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on May 9, 2003 is withdrawn in view of the Amendment received on November 6, 2003.

***New Rejection – Necessitated by Amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The instant rejection is necessitated by the newly submitted claims 56-71, submitted in the Amendment received on November 6, 2003.

Claims 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 64-66 recite the limitation "the protein of claim 62." However, claim 62 is drawn to an isolated polypeptide. There is insufficient antecedent basis for this limitation in the claim. Amending the claims to recite "the polypeptide of claim 62," would overcome this rejection.

***Claim Rejections - 35 USC § 102***

The rejection of claims 11, 12, and 24-55 under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US 2003/0073129 A1, published April 17, 2003, priority September 1, 1998), made in the Office Action mailed on July 28, 2003 is withdrawn in view of the arguments presented in the Amendment received on November 6, 2003, demonstrating (and upon verification) that earlier filed provisional application, specifically, U.S. Serial No. 60/074,157, which antedates the Baker reference, had support for the instantly claimed protein.

***Double Patenting (Duplicate Claims)***

The instant Double Patenting objection is necessitated by the newly submitted claims 67-71, submitted in the Amendment received on November 6, 2003.

Claims 67-71 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 51-55.

On page 10, 2<sup>nd</sup> paragraph of Applicants' response states that, "Applicants assert that present claimed amino acid SEQ ID NO: 108 corresponds to clone HHEPU32, which relies on the same cDNA sequence contained in ATCC Deposit No. 290603..." Based on this assertion the claims are duplicate and though slight difference in wording, the claims cover the same subject matter. For example, claim 67 is drawn to an isolated protein consisting of a fragment of SEQ ID NO: 108, wherein said fragment is at least 30 contiguous amino acid residues in length, while claim 51 is drawn to an isolated protein consisting of a fragment of the complete polypeptide encoded by the HHEPU32 cDNA contained in ATCC Deposit No. 209603, wherein said fragment is at least 30 contiguous amino acid residues in length.

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Since Applicants assert that HHEPU32 cDNA encodes the polypeptide of SEQ ID NO: 108, both claims are drawn to a fragment of a protein of SEQ ID NO: 108, wherein said fragment is at least 30 contiguous amino acid residues in length. For claims 68-71 and 52-55, the same reasoning applies.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Conclusion***

Claims 17 and 19 remain withdrawn. Claims 20 and 67-71 are objected to.

Claims 64-66 are rejected. Claims 30-35, 41-45, and 51-63 are allowed.

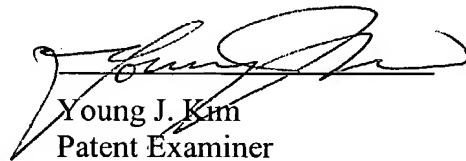
### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official

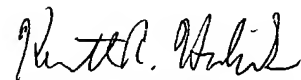


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documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
1/29/04



KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

2/4/04